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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,594	11/07/2001	Atul D. Ayer	ARC 2483N2	8494

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EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/04/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/005,594

Applicant(s)

AYER ET AL.

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicants' response, request for continued examination, petition for extension of time, and terminal disclaimer, all received on 06 August 2003.

Terminal Disclaimer

The terminal disclaimer filed on 06 August 2003 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of U.S. Patent No. 6,096,339, has been reviewed and is accepted. The terminal disclaimer has been recorded.

Double Patenting

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 39-53 under the judicially created doctrine of obviousness-type double patenting is hereby withdrawn with the filing and subsequent acceptance of the applicants' terminal disclaimer.

Claim Objections

Claim 51 objected to because of the following informalities: In the claim as currently filed, the 4th line of the claim (“(a) admitting orally...”) is immediately followed by a duplication of that same line. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39-46 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 39, at least one line appears to be missing from the claim as currently filed. The claim currently lists only method steps (a), (c), and (d). The omission of at least one line in this claim renders its scope such that it is not completely ascertainable. As Claims 40 and 41 both depend upon Claim 39, by extension, the scope of these claims is also unclear.

In Claims 42 and 46, steps (a), (b), and (d) are so vague as to render the scope of these claims unascertainable. No positive method steps are recited that disclose how such particle sizes are controlled, or of how exactly the means for prolonging the release of the drug is provided. As Claims 43-45 all depend upon Claim 42, by extension, the scope of these claims is also unclear.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 39-53 under 35 U.S.C. 103 over Jao *et al.* is maintained.

Response to Arguments

Applicant's arguments filed 06 August 2003 have been fully considered but they are not persuasive.

It is the position of the examiner that the drug release profiles disclosed by the prior art demonstrates a sufficiently uniform drug release that one of ordinary skill in the art can through routine experimentation, formulate a dosage that satisfies the limitations of the instant claims. The manufacture of a drug composition exhibiting a substantially zero-order rate of drug release is an aim that has been long desired in the art (See Jao *et al.*, Columns 17 and 18). To this end, it is the position of the examiner that the manufacture of a dosage form satisfying the instantly claimed features of drug release are inherent in the prior art. The examiner further points to the substantially similar materials used both in the prior art and in the instant application (See Jao *et al.*, Examples). The burden is upon the applicant to prove that the instantly claimed features of substantially non-deviating drug release could not have been achieved by the methods of the prior art, as well as to prove that such features are not inherent in the prior art.

Furthermore, the applicant has not shown a patentable distinction of the particle size claim limitations in the instant claims that would make such limitations critical in the formulation of a dosage form exhibiting uniform drug release that the examiner believes is already disclosed in the prior art. Please note that by "routine experimentation" as stated above, the examiner intends to mean the optimization and adjustment of parameters not necessarily restricted to the adjustment of particle size alone. As the previously mentioned by the examiner, the figures presented in the prior art show what the examiner believes to be drug release profiles that fit the limitations set forth in the instant claims, despite the absence of limitations drawn to

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particle sizes. As such, the examiner must bring into question the criticality of such claim limitations. Currently, it is the position of the examiner that the applicant's claimed invention of the prior art lies within the scope of the disclosure prior art and the rejection of the instant claims is deemed proper.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Examiner
Art Unit 1615

sj0

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600